MAY 07 2002

K020720

510(k) summary

(As Required by Section 807.92 (c))

1. Name: Unicare Biomedical, Inc.
   Address: 25951 La Cuesta Avenue, Laguna Hills, CA 92653
   Contact: Stan Yang, 949-643-6707
   Date: February 28, 2002

2. Trade Name: Ossiform
   Common Name: Synthetic bone graft material
   Classification Name: Endosseous implant for bone filling and augmentation
   Device Classification: Unclassified

3. Device Description
   Ossiform is a synthetic bioactive glass that is intended for use in the repair of oral/maxillofacial and dental intraosseous defects. The bioactive glass granules are supplied sterile in a polyolefin vial within a sealed pouch.

4. Predicate Devices
   The Ossiform device is substantially equivalent to devices currently in US commercial distribution, which are classified as endosseous implant for bone filling and augmentation. Examples of such products include Unigraft®, PerioGlas® and BioGran®. These products are made of bioactive ceramic materials with similar performance.

5. Intended Use
   Ossiform is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including: periodontal defects, ridge augmentation, extraction sites, cranio-facial augmentation, sinus lifts and cystic defects

6. Device Testing
   The performance of Ossiform was evaluated using a variety of test methods. The results of these tests demonstrate that Ossiform is substantially equivalent to a predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 07 2002

Mr. Stan Yang
Vice President
Unicare BioMedical, Incorporated
25951 La Cuesta Avenue
Laguna Hills, California 92653

Re: K020720
Trade/Device Name: OSSIFORM
Regulation Number: None
Regulation Name: Endosseous Implant
Regulatory Class: Unclassified
Product Code: LYC
Dated: March 1, 2002
Received: March 5, 2002

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020720

510(K) NUMBER:

DEVICE NAME: OSSIFORM

INDICATIONS FOR USE:

Ossiform is intended to fill and/or augment dental intraosseous and oral/maxillofacial defects including: periodontal defects, sinus lifts, cystic defects, extraction sites, cranio-facial augmentation and augmentation of the alveolar ridge.

Concurrence of CDRH, Office of device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020720